DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

42 CFR Parts 431, 433, 435, 436, and 457; Subchapters D through G

[HCFA-2006-F]

RIN 0938-AI28

State Child Health; Implementing Regulations for the State Children's Health Insurance Program

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Final rule.

SUMMARY: Section 4901 of the Balanced Budget Act of 1997 (BBA) amended the Social Security Act (the Act) by adding a new title XXI, the State Children's Health Insurance Program (SCHIP). Title XXI provides funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. To be eligible for funds under this program, States must submit a State plan, which must be approved by the Secretary.

This final rule implements provisions related to SCHIP including State plan requirements and plan administration, coverage and benefits, eligibility and enrollment, enrollee financial responsibility, strategic planning, substitution of coverage, program integrity, certain allowable waivers, and applicant and enrollee protections. This final rule also implements the provisions of sections 4911 and 4912 of the BBA, which amended title XIX of the Act to expand State options for

coverage of children under the Medicaid program. In addition, this final rule makes technical corrections to subparts B, and F of part 457.

EFFECTIVE DATE: This final rule is effective 90 days after date of publication in the **Federal Register**. To the extent contract changes are necessary, however, States will not be found out of compliance until the next contract cycle. By contract cycle, we mean the earlier of the date of the original period of the existing contract, or the date of any modification or extension of the contract (whether or not contemplated within the scope of the contract).

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I. Background

Section 490l of the BBA, Public Law 105-33, as amended by Public Law 105-100, added title XXI to the Act. Title XXI authorizes the SCHIP program to assist State efforts to initiate and expand the provision of child health assistance to uninsured, low-income children. Under title XXI, States may provide child health assistance primarily for obtaining health benefits coverage through (1) a separate child health program that meets the requirements specified under section 2103 of the Act; (2) expanding eligibility for benefits under the State's Medicaid plan under title XIX of the Act; or (3) a combination of the two approaches. To be eligible for funds under this program, States must submit a State child health plan (State plan), which must be

approved by the Secretary.

The State Children's Health Insurance Program is jointly financed by the Federal and State governments and is administered by the States. Within broad Federal guidelines, each State determines the design of its program, eligibility groups, benefit packages, payment levels for coverage, and administrative and operating procedures. SCHIP provides a capped amount of funds to States on a matching basis for Federal fiscal years (FY) 1998 through 2007. At the Federal level, SCHIP is administered by the Department of Health and Human Services, through the Center for Medicaid and State Operations (CMSO) of the Health Care Financing Administration (HCFA). Federal payments under title XXI to States are based on State expenditures under approved plans effective on or after October 1, 1997.

This final rule implements the following sections of title XXI of the Act:

- Section 2101 of the Act, which sets forth the purpose of title XXI, the requirements of a State plan, State entitlement to title XXI funds, and the effective date of the program.
- Section 2102 of the Act, which sets forth the general contents of a State plan, including eligibility standards and methodologies, coordination, and outreach.
- Section 2103 of the Act, which contains coverage requirements for children's health insurance.

• The following parts of section 2105 of the Act: 2105(c)(2)(B), which relates to cost-effective community based health delivery systems; 2105(c)(3), which relates to waivers for purchase of family coverage; 2105(c)(5), which relates to offsets for cost-sharing receipts, and 2105(c)(7) which relates to limitations on payment for abortion.

• Section 2106 of the Act, which describes the process for submission and approval of State child health plans and plan amendments.

• Section 2107 of the Act, which sets forth requirements relating to strategic objectives, performance goals and program administration.

• Section 2108 of the Act, which requires States to submit annual reports and evaluations of the effectiveness of the State's title XXI plan.

• Section 2109 of the Act, which sets forth the relation of title XXI to other laws.

• Section 2110 of the Act, which sets forth title XXI definitions.

This final rule also implements the provisions of sections 4911 and 4912 of the BBA, that amended title XIX of the Act to provide expanded coverage to children under the Medicaid program. Specifically, section 4911 of the BBA set forth provisions for use of State child health assistance funds for enhanced Medicaid

match for expanded eligibility under Medicaid to provide medical assistance to optional targeted low-income children. Section 4912 of the BBA added a new section 1920A to the Act creating a new option to provide presumptive eligibility for children. Both title XXI and title XIX statutory provisions are discussed in detail in section II. of this preamble.

This final rule also implements section 704 of the Balanced Budget Refinement Act of 1999 (BBRA, Public Law 106-113), enacted on November 29, 1999, which requires the Secretary to refer to the title XXI program as the "State Children's Health Insurance Program" or "SCHIP" in any publication or other official communication.

We note that on May 24, 2000, HCFA published in the **Federal Register** a final rule (HCFA 2114-F) concerning financial program allotments and payments to States under SCHIP at (65 FR 33616). In that rule, we implemented section 2104 and portions of section 2105 of the Act, which relate to allotments and payments to States under title XXI. For a detailed discussion of title XXI and related title XIX financial provisions, including the allotment process, the payment process, financial reporting requirements and the grant award process, refer to the May 24, 2000 final rule (65 FR 33616). Please note that, to eliminate duplication and provide clarity, this final rule also amends selected sections of the financial rule within Subpart B.

II. Provisions of the Proposed Rule and Discussion of Public Comments

A. Overview

1. Summary of proposed provisions and significant revisions in this final rule.

On November 8, 1999, we published a proposed rule that set forth the programmatic provisions of the State Children's Health Insurance Program (64 FR 60882). The provisions of the proposed regulation were largely based on previously released guidance, and therefore represented policies that had been in operation for some time. In the proposed rule, we identified a number of areas in which we elaborated on previous guidance or proposed new policies.

We received 109 timely comments on the proposed rule. Interested parties that commented included States, advocacy organizations, individuals, and provider organizations. The comments received varied widely and were often very detailed. We received a significant number of comments on the following areas: State plan issues, such as when an amendment to an existing plan is needed; information that should be provided or made available to potential applicants, applicants and enrollees; the exemption to cost sharing for American Indian/Alaska Native children; eligibility and "screen and enroll" requirements; Medicaid coordination issues; eligibility simplification options such as

presumptive eligibility; the definition of a targeted low-income child; substitution of private coverage; data collection on race, ethnicity, gender and primary language; grievance and appeal procedures and other enrollee protections; and premium assistance for employer-sponsored coverage.

All public comments have been summarized and are discussed in detail in section II below. A brief summary of key issues discussed in the proposed rule as well as significant revisions made in this final rule follows:

- **Subpart A -- State Plan Requirements**

The proposed regulation included several conditions under which States must submit amendments to approved SCHIP plans. For example, we proposed that a State must submit a plan amendment when the funding source of the State share changes, prior to such change taking effect. In addition, we proposed that amendments to impose cost sharing on beneficiaries, increase existing cost-sharing charges, or increase the cumulative cost-sharing maximum considered the same as amendments proposing a restriction in benefits. We noted that States would be required to follow rules regarding prior public notice and retroactive effective dates for these amendments.

The final regulation clarifies several issues surrounding the circumstances under which amendments must be submitted. It lists more clearly the program changes that must be included in

the State plan by submitting an amendment. In addition, the final rule modifies the budget requirements to require a 1-year projected budget for those amendments that have a significant budgetary impact. Budgets are no longer required with every State plan amendment; however States must submit a 3-year projected budget with its annual report (discussed in subpart G). Finally, States must submit an amendment before making changes in the source of the non-Federal share of funding.

We have provided additional clarification with regard to the requirements for coordination between SCHIP and Medicaid, as well as coordination with other public programs. We have modified the regulation text to further emphasize the need for coordination with other public programs after screening for Medicaid eligibility during the SCHIP application process, as well as assisting in enrollment in SCHIP of children determined ineligible for Medicaid.

The section laying out provisions for enrollment assistance and information requirements has been modified to include the provision of linguistically appropriate materials to families of potential applicants, applicants and enrollees in SCHIP to assist them in making informed health care decisions about their health plans, professionals and facilities. We have also clarified that, in addition to information about the types of benefits and participating providers. In addition, States must inform

applicants and enrollees about their rights and responsibilities regarding procedures for review of adverse decisions regarding eligibility or health services decisions and the circumstances under which they may be subject to enrollment caps and waiting lists.

- **Subpart C -- Eligibility, Screening, Applications and Enrollment**

The proposed rule outlined provisions for eligibility and enrollment for separate child health programs and implementation of the "screen and enroll" requirement. It also included the title XXI restrictions on the participation of children of public agency employees who are eligible to participate in a State health benefits plan, children who are residing in institutions for mental disease (IMDs), and children who are inmates of public institutions.

The final rule further elaborates on issues surrounding eligibility, enrollment and ensuring that children eligible for Medicaid benefits are enrolled in Medicaid. We have modified the definition of "targeted low-income child" to parallel a modification to the definition of "optional targeted low-income child" under the Medicaid regulations. This modification effectively excludes from title XXI "maintenance of effort" provisions certain section 1115 demonstrations that were in place on March 31, 1997, but that were so limited in scope that we do

not consider them to be equivalent to Medicaid.

We clarified the standards for eligibility for separate child health programs, including: 1) clearly permitting self-declaration of citizenship; 2) prohibiting durational residency requirements; 3) prohibiting lifetime caps or other time limits on eligibility; 4) permitting 12-months of continuous eligibility; and 5) permitting enrollment caps and waiting lists when approved as part of the State plan. In addition, we have specifically required States to implement standards for conducting eligibility determinations and a process that does not exceed 45 days (excluding days during which the application has been suspended).

The rule provides further clarification of the issues surrounding children of public employees, children in IMDs and children who are inmates of public institutions. For example, we clarified that the children of public employees are eligible only if the employer contribution under a State health benefits plan is no more than a nominal contribution of $10 per family, per month. We also modified the definition of “State health benefits plan” to exclude separately run county, city, or other public agency plans that receive no State contribution toward the cost of coverage and in which no State employees participate.

The final rule also further clarifies the requirements for treatment of children found to be potentially eligible for

Medicaid after applying for coverage under a separate child health program. In order to ensure the effectiveness of the screening mechanisms, States are required to establish a system for monitoring the screen and enroll process. Finally, the rule lays out procedures for States that opt to provide presumptive eligibility for the separate child health program while the application and eligibility determination process is underway.

- **Subpart D -- Coverage and Benefits**

The proposed rule provided for some flexibility for States in keeping the SCHIP benefit package current. A State using the benchmark benefit package option is not required to submit an amendment each time the benchmark package changes, as long as it continues to offer the same benefits covered under the approved State plan. However, States must submit an amendment to their State plan any time the benefits offered to enrollees change. If the change in benefits is intended to conform the separate State benefit package to the benchmark coverage, then the benefit package remains benchmark coverage. But if the change in benefits causes the State-offered benefits to differ from the benchmark coverage, then the benefits must be reclassified as benchmark equivalent or one of the other benefit package options.

The proposed rule included the requirement that States use the “prudent layperson standard” in defining coverage for emergency services under SCHIP. The proposed rule also required

use of the American Committee on Immunization Practices(ACIP) schedule for age-appropriate immunizations.

The final rule retains all of the same provisions as included in the proposed rule. In addition, for purposes of clarity, we have moved a provision formerly found in Subpart G, Strategic Planning, Reporting, and Evaluation into this Subpart. The provision, entitled “State assurance of access to care and procedures to assure quality and appropriateness of care” includes the requirements for assuring access to covered services, including emergency services, well-baby, well-child and well-adolescent care, and age appropriate immunizations. This provision also requires States to assure appropriate and timely procedures to monitor and treat enrollees with chronic, complex, or serious medical conditions, including access to an adequate number of visits to specialists experienced in treating the specific medical condition. Finally, this provision requires States to assure decisions related to the provision of health services are completed within 14 days of the request for the service, in accordance with the medical needs of the child.

- **Subpart E -- Enrollee Financial Responsibilities**

Title XXI permits States to impose cost sharing on enrollees in separate child health programs, but places a 5 percent cap on the amount of cost-sharing expenditures for families with incomes greater than 150 percent of the Federal Poverty Level (FPL). In

an attempt to preserve State flexibility, we proposed to give States the option to use either gross or net family income when calculating this cost-sharing cap for families. In addition, we proposed to place a limit of 2.5 percent on cost sharing for families with incomes at or below 150 percent of the FPL, in order to ensure that those families with lower incomes will not be required to spend the same percentage of their income on cost sharing as those with higher incomes. Many commenters supported the need for this distinction, given the more limited amount of disposable income in such families. Under the proposed rule, States also had the option to apply medical costs for non-covered or non-eligible family members toward the cumulative maximum cap.

We proposed that States must have a process in place that will protect enrollees by ensuring an opportunity to pay past due cost-sharing amount before they can be disenrolled from the program for failure to pay cost sharing. We suggested that States should look for a pattern of nonpayment, and provide clear notice and opportunities for late payment before taking action to disenroll.

Finally, title XXI includes provisions to ensure enrollment and access to health care services for American Indian and Alaska Native (AI/AN) children. The proposed regulation incorporated our interpretation that in light of the unique Federal relationship with tribal governments, cost-sharing requirements

for individuals who are members of a Federally recognized tribe are not consistent with this statutory requirement.

The final rule clarifies that States must provide to the family of each individual SCHIP enrollee, the cumulative cost-sharing maximum amount for that year. In addition, this subpart confirms that the State plan must clearly describe a State's cost-sharing policy in terms of which children will be subject to cost sharing, the consequences for enrollees who do not pay a charge, and the disenrollment protections provided to enrollees in the event that they do not pay the cost sharing. States must also describe the methodology to ensure that families do not exceed the cumulative cost-sharing maximum and assure that families will not be held liable for cost-sharing amounts, beyond the copayment amounts in the State plan, for emergency services provided outside of an enrollee's managed care network.

The final rule confirms the protections included in the proposed rule related to AI/AN children and clarifies that States may use self-declaration of tribal membership for identifying AI/AN children in order to facilitate implementation of the cost-sharing exemption.

The final rule continues to require that States may not impose more than one type of cost sharing on a service; and that States may only impose one copayment based on the total cost of services furnished during one office visit.

Finally, States must provide enrollees with an opportunity to show that their family income has declined before being disenrolled for failure to pay cost sharing, because the child may have become eligible for a category with lower or no cost sharing if family income has declined. States must also provide enrollees with an opportunity for an impartial review to address disenrollment from the program for this reason (see discussion of new Subpart K, Applicant and Enrollee Protections).

- **Subpart G -- Strategic Planning, Reporting and Evaluation**

The proposed regulation included provisions intended to ensure compliance with the statute and the elements of the State's approved title XXI plan. This subpart included the essential elements of strategic objectives and performance measures to assist the States and the Federal government in assessing the effectiveness of the SCHIP program in increasing the number of children with health insurance, and an assessment of the quality of and access to needed health care services.

The proposed rule also outlined the quarterly statistical reporting requirements and the required elements of States annual reports and the March 31, 2000 SCHIP evaluation.

The final rule confirms these requirements and further describes data elements to be reported by the States, including data on gender, race, ethnicity, and primary language. The gender, race and ethnicity data will be required in the State's

quarterly statistical enrollment reports; and the annual reports will include a description of data regarding the primary language of SCHIP enrollees. In addition, the annual reports will include an updated budget for a 3-year period, including any changes in the source of the non-Federal share of State plan expenditures. The annual reports must also include description of the State's current income eligibility standards and methodologies.

Finally, the final rule notes the Secretary's intention to develop, with input from States, academic and intergovernmental organizations, a core set of national performance goals and measures. When developed, States will also be required to report on these measures in their annual reports.

- **Subpart H -- Substitution of Coverage**

The proposed rule set forth requirements for ensuring that States have in place mechanisms aimed at preventing substitution of public coverage for private group coverage. With respect to coverage provided directly through SCHIP, the preamble included a description of HCFA's three-tiered policy to apply increased scrutiny to States' substitution prevention strategies at higher incomes. For coverage provided through premium assistance for employers' group health plans, the proposed rule set forth specific requirements for a six-month period of uninsurance and a minimum 60 percent employer premium contribution.

Due to a general lack of evidence of the existence of

substitution below 200 percent of the FPL and the significant number of comments received on this subpart, we have revised the final rule to clarify our policy related to substitution. The preamble to the final rule clarifies that for coverage provided other than through premium assistance programs, we will no longer require a substitution prevention strategy for families with incomes below 250 percent of the FPL. Instead, States will be required to monitor the occurrence of substitution below 200 percent of the FPL. Between 200 and 250 percent of the FPL, we will work with States to develop procedures, in addition to monitoring, to prevent substitution that would be implemented in the event that an unacceptable level of substitution is identified. Above 250 percent of the FPL, States must have a substitution prevention mechanism in place, however we encourage States to use other strategies than waiting periods.

For States wishing to utilize premium assistance programs, we have revised the final rule to provide additional flexibility. While we have retained the 6-month waiting period without group health plan coverage, States have flexibility to include a number of exceptions for circumstances such as involuntary loss of coverage, economic hardship, and change to employment that does not offer dependent coverage. We have also removed the requirement for States to demonstrate an employer contribution of at least 60 percent when providing coverage through premium

assistance programs. Rather, we have clarified that States must demonstrate cost-effectiveness of their proposals by identifying a minimum contribution level and providing supporting data to show that the level is representative of the employer-sponsored insurance market in their State.

Finally, the final rule provides that the Secretary has discretion to reduce or waive the minimum period without private group health plan coverage.

- **Subpart I -- Program Integrity**

The provisions in this subpart are intended to preserve program integrity in the State Children's Health Insurance Program. We proposed that States must have fraud and abuse protections in place, but provided flexibility to States in developing program integrity protections for separate child health programs. States with separate child health programs may utilize systems already existing for Medicaid, but are not required to do so. In addition, we proposed that States have additional flexibility in setting procurement standards more broadly than are available under Medicaid. We proposed that States may choose to base payment rates on public and/or private rates for comparable services for comparable populations, and where appropriate, establish higher rates in order to ensure sufficient provider participation and access.

Finally, the proposed regulation included various enrollee

protections consistent with the President's directive regarding the *Consumer Bill of Rights and Responsibilities*, including provisions regarding grievances and privacy protections. In response to public comment about the need for consistency of provisions throughout the final rule, we have moved the overview of the enrollee protections to the preamble of this final rule, but have removed it from the final regulation text, as it repeated the protections included throughout the proposed rule. The discussion of enrollee protections is now found in subpart K -- Applicant and Enrollee Protections.

The final rule confirms the significance of maintaining program integrity in SCHIP and clarifies issues related to the certification of data that determines payment and the development of actuarially sound payment rates. It notes that States should base payment rates on public and/or private rates for comparable services for comparable populations, consistent with the principles of actuarial soundness. We have also moved the subsection formerly entitled, "Grievances and appeals" to the new Subpart K, where these requirements are retained and elaborated upon.

Finally, the rule confirms the importance of maintaining the integrity of professional advice to enrollees by requiring compliance with the provisions of the final Medicare+Choice rule that prohibit interference with health care professionals' advice

to enrollees; require that professionals provide information about treatment options in an appropriate manner; limits physician incentive plans; and provides requirements related to information disclosure related to physician incentive plans.

- **Subpart J -- Waivers**

The proposed rule noted the requirements for obtaining a waiver to provide coverage through a community-based delivery system and discussed the circumstances under which a State may obtain a waiver in order to provide title XXI coverage to entire families. We proposed that in order to qualify for a family coverage waiver, the State must meet several requirements, including a requirement that the proposal be cost-effective.

In the final rule, we have clarified that the provisions of this subpart apply to separate child health programs. The provisions apply to Medicaid expansions only in cases where the State files claims for administrative costs under title XXI and seeks a waiver of limitations on such claims for coverage under a community-based health delivery system. We have clarified that HCFA will review requests for waivers under this subpart using the same time frames (the 90-day review clock) as those used for the review of State plan amendments under SCHIP. In addition, in response to comments received on this subpart, we have extended the approval period for the waivers to provide coverage through a community based delivery system from two years to three years in

an attempt to better align with the period of availability for SCHIP allotments.

With regard to the family coverage waiver, the final rule clarifies that when applying the cost-effectiveness test, States must assess cost-effectiveness in its initial request for a waiver, and then annually. States may do the assessment either on a case-by-case basis or in the aggregate.

- **Subpart K -- Applicant and Enrollee Protections**

The proposed rule emphasized the importance of enrollee protections by including many of the elements of the *Consumer Bill of Rights and Responsibilities* throughout the rule. In addition, an overview of these protections was presented in Subpart I -- Program Integrity and Beneficiary Protections. We received several comments on our decision to implement the CBRR through this regulation. While we have retained the protections included in the proposed rule in the appropriate location as related to the issue, we have attempted to clarify the required protections by creating a new subpart dedicated to privacy and a process for review of certain eligibility and health services matters, Subpart K -- Applicant and Enrollee Protections.

We have included more specific requirements than those that were included in Subpart I of the proposed rule and will require the State plan to include a description of the State’s process for review and resolution of eligibility and enrollment matters

such as denial or failure to make a timely determination of eligibility, and suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States must also provide enrollees with an opportunity for external review of health services matters, such as delay, denial, reduction, suspension or termination of health services, in whole or in part; and the failure to approve, furnish, or provide payment for health services in a timely manner. Exceptions to these requirements can be made in the event that the sole basis for such a decision is a change in the State plan or a change in Federal or State law that affects all or a group of applicants or enrollees without regard to their individual circumstances.

The final rule lays out requirements for the core elements of review of eligibility or health services matters, and requires that the reviews be impartial, conducted by a person or entity that has not been directly involved or responsible for the matter under review. The rule also establishes a 90-day time frame within which external reviews (or a combination of an internal and an external review) must be completed. States should take into consideration the medical needs of the patient when conducting the reviews and provide expedited time frames if an enrollee’s physician determines that a longer time frame could seriously jeopardize the enrollees life, health or ability to attain or regain maximum function. If the enrollee has access to

both internal and external review, each level of expedited review may take no more than 72 hours.

The final rule requires States to provide continuation of enrollment pending the completion of review of a suspension or termination of enrollment, including disenrollment for failure to pay cost sharing. States must also provide enrollees with timely written notice of any determinations subject to review including the reasons for the determination, an explanation of applicable rights to review, the time frames for review, and circumstances under which enrollment may continue pending a review.

Finally, the rule provides an exception for States that operate premium assistance programs under SCHIP. If the State utilizes a premium assistance program that does not meet the requirements for review under this Subpart, the State must give applicants and enrollees the option to enroll in the non-premium assistance program in the State. States must provide this option at initial enrollment and at each renewal of eligibility.

• Expanded Coverage of Children under Medicaid and Medicaid Coordination

In this section we set forth our changes to the Medicaid regulations that allow for expanded coverage of children under title XIX. Although these regulations are related to title XXI and SCHIP, they are changes to the Medicaid program and all existing Medicaid regulations also apply. We set forth

requirements related to presumptive eligibility for children, the enhanced FMAP (Federal medical assistance percentage) rate for children, and the new group of optional targeted low-income children established by the statute. The presumptive eligibility provisions have been clarified in this final rule to lay out specific notification requirements and establish procedures for making presumptive eligibility determinations and expands the definition of "qualified entity" in accordance with the Benefits Improvement and Protection Act of 2000 (BIPA). Finally, the rule establishes consistent coordination requirements between Medicaid and SCHIP.

2. General Comments

In this section, we have summarized and responded to general public comments on the SCHIP programmatic regulation. These comments relate to the program or the proposed rule as a whole and not to any particular provision of the proposed rule. All other public comments are addressed below in the context of the relevant subpart.

Comment: We received a great number of comments discussing the issue of providing SCHIP coverage through premium assistance programs. Many commenters noted the difficulty that States would have in requiring employer plans to meet the proposed requirements. Many commenters argued that the proposed rule imposed too many requirements on SCHIP coverage obtained through

employer-sponsored insurance and that the proposed provisions would stifle State innovation in utilizing such insurance.

Response: At the time of publication of the proposed rule, the experience with premium assistance programs in SCHIP had been limited to only a few States. Therefore, the proposed regulation did not include a great deal of specificity regarding the regulation's applicability to premium assistance models. We have attempted to provide States with flexibility, while ensuring that States meet their statutory obligation to all SCHIP enrollees regardless of the insurance product being provided. Further, it would not be consistent with the SCHIP statute to exempt certain enrollees from the protections established by law, simply because of the delivery model. However, we also recognize the value and the increased potential for reaching children associated with interaction with the employer-based insurance market. Thus, while we will ensure compliance with the protections set forth in this final rule, we look forward to working closely with States to help in the development and approval of proposals that utilize premium assistance programs. As noted in the overview section, we have provided some additional flexibility in subpart H, Substitution, with respect to premium assistance programs that we hope will facilitate increased use of premium assistance programs in SCHIP. We have also provided some flexibility with regard to certain enrollee

protections in subpart K.

Comment: One commenter noted that there is an inequity in funding that disadvantages States that expanded eligibility prior to March 31, 1997. Another commenter indicted that it is difficult for States that had expanded Medicaid to high levels prior to March 31, 1997 to access SCHIP funds and suggested that States be allowed to use SCHIP funds to subsidize employer-sponsored insurance.

Response: We recognize the inequities that have been caused by the "maintenance of effort" provision in the SCHIP statute, which holds States to the current eligibility levels in effect on March 31, 1997, and we applaud States that were progressive in expanding their Medicaid programs through section 1115 demonstrations and through the flexibility provided under section 1902(r)(2) and section 1931 of the statute. However, the maintenance of effort provision in the SCHIP statute was put in place specifically to ensure that States did not roll back the eligibility and benefits standards that were in place prior to the existence of SCHIP, and to encourage further expansion in implementing States' SCHIP programs.

Comment: Several commenters asserted that the proposed regulations were overly prescriptive, limit State flexibility, and raise program administrative costs. Several commenters specifically complained that the proposed regulations appeared to

push States toward Medicaid or Medicaid-like programs. Some commenters asserted that the overall approach directly contradicted Executive Order 13132 on Federalism. Some argued that the regulations should be limited to areas Congress specifically required the Secretary to address in regulations, the administrative review process for State plans, or to clarification of essential terms. While some commenters recognized the need for federal guidance, they supported the inclusion of such guidance in the preamble and other guidance documents rather than in the regulation text.

Response: In developing the proposed and final regulations, we have taken great care to try to balance the need to ensure that SCHIP will provide the full intended benefits to uninsured, low-income children with the goal of retaining as much State flexibility as possible. HCFA has tried to administer the program and develop policies in a manner that gives States a full opportunity to develop programs that met local needs, whether through a Medicaid expansion or a separate child health program.

To make it possible for States to develop and implement their programs, from the time of enactment of the SCHIP program, HCFA has worked with States to disseminate as much information as possible, as quickly as possible. In the first three months of the program's existence, we released over 100 answers to frequently asked questions and issued several policy guidance

letters. We continue to take into consideration the changing needs of States. The programs that States developed vary in scope, delivery system and many other respects. The diversity and innovation that has been displayed is an indication that State flexibility does indeed exist.

In addition, we consulted with State and local officials in the course of the design and review stages of State proposals, and many of the policies found in the proposed and this final rule are a direct result of these discussions and negotiations with the States. To the extent consistent with the objectives of the statute, to obtain substantial health care coverage for uninsured low-income children in an effective and efficient manner, we have endeavored to preserve State options in implementing their programs.

We developed these final regulations with the goal of providing a balanced view of both Medicaid expansions and separate child health programs. We made careful determinations as to whether each subpart should be applicable to separate child health programs and Medicaid expansions, or only to separate programs. In doing this, we have attempted to maximize flexibility and avoid the need for duplication of effort, while at the same time recognizing the basic differences between the two approaches.

We believe our considerations, and the consultative process

we followed during the State plan review process, fully comported with the requirements of Executive Order 13132, and the final regulations contain the framework necessary for States to achieve the statutory requirements and objectives set forth by Congress.

Comment: Several commenters were concerned that the proposed regulations would narrow available State options, with particular mention of barriers to private sector models, and impose additional burdensome requirements on States. Some commenters was concerned that the proposed regulations would require administrative costs that would be a difficult financial burden for a small separate child health program.

Response: We recognize the commenters' concern and have tried to keep potential administrative burden in mind in developing these regulations. Some administrative investment, however, is necessary to ensure proper delivery of health care coverage to uninsured low-income children, and to provide enrollees with protections to ensure that such coverage is furnished in an effective and efficient manner that is coordinated with other sources of health benefits coverage for children.

3. Table of Contents for part 457

We set forth the new provisions for the State Children's Health Insurance Program in regulations at 42 CFR part 457, subchapter D. We note that the following table of contents is

for all of part 457 and lists some subparts which have been reserved for provisions set forth in the May 24, 2000 final financial regulation (65 FR 33616).

Subchapter D -- State Children's Health Insurance Program (SCHIP)

Part 457 -- Allotments and Grants to States

Subpart A -- Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

Sec.

Subpart H -- Substitution of Coverage

Subpart I -- Program Integrity

B. Subpart A -- Introduction; State Plans for Child Health Insurance Programs and Outreach Strategies

1. Program description (§457.1)

In proposed §457.1, we set forth a description of the State Children's Health Insurance Program. Title XXI of the Social Security Act, enacted in 1997 by the BBA, authorizes Federal grants to States for provision of child health assistance to uninsured, low-income children. The program is jointly financed by the Federal and State governments and administered by the States. Within broad Federal rules, each State decides eligible groups, types and ranges of services, payment levels for benefit coverage, and administrative and operating procedures. We received no comments on this section and have retained the proposed language in this final rule.

2. Basis and scope of subchapter D (§457.2)

Proposed §457.2 set forth the basis and scope of subchapter D. This subchapter implements title XXI of the Act, which authorizes Federal grants to States for the provision of child health assistance to uninsured, low-income children.

The regulations in subchapter D set forth State plan requirements, standards, procedures, and conditions for obtaining Federal financial participation (FFP) to enable States to provide health benefit coverage to targeted low-income children, as defined in §457.310. We received no comments on this section and

have retained the proposed language in this final rule.

3. Definitions and use of terms(§457.10)

This subpart includes the definitions relevant specifically to the State Children's Health Insurance Program under title XXI. In this subpart, we defined key terms that are specified in the statute or frequently used in this regulation. We note that those terms that are specific to certain subparts of this regulation are defined at the opening of each subpart, however, all the terms are listed here. Because of the unique Federal-State relationship that is the basis for this program and because of our commitment to State flexibility, States have the discretion to define many terms.

We proposed the following definitions:

- American Indian/Alaska Native (AI/AN) means (1) a member of a Federally recognized Indian tribe, band, or group or a descendant in the first or second degree, of any such member; (2) an Eskimo or Aleut or other Alaska Native enrolled by the Secretary of the Interior pursuant to the Alaska Native Claims Settlement Act 43 U.S.C. 1601 *et seq*; (3) a person who is considered by the Secretary of the Interior to be an Indian for any purpose; (4) a person who is determined to be an Indian under regulations promulgated by the Secretary.
- Child means an individual under the age of 19.
- Child health assistance has the meaning assigned in

§457.402.

• State Children's Health Insurance Program (SCHIP) means a program established and administered by a State, but jointly funded with the Federal government to provide child health assistance to uninsured, low-income children through a separate child health program, a Medicaid expansion program, or a combination of both.

• Combination program means a program under which a State provides child health assistance through both a Medicaid expansion program and a separate child health program.

• Contractor has the meaning assigned in §457.902.

• Cost-effective has the meaning assigned in §457.1015.

• Creditable health coverage has the meaning given the term "creditable coverage" at 45 CFR 146.113. Under this definition, the term means the coverage of an individual under any of the following:

-- A group health plan (as defined in 45 CFR 144.103).

-- Health insurance coverage (as defined in 45 CFR 144.103).

-- Part A or part B of title XVIII of the Act (Medicare).

-- Title XIX of the Act, other than coverage consisting solely of benefits under section 1928 (the program for distribution of pediatric vaccines).

-- Chapter 55 of title 10, United States Code (medical and

dental care for members and certain former members of the uniformed services, and for their dependents).

-- A medical care program of the Indian Health Service or of a tribal organization.

-- A State health benefits risk pool (as defined in 45 CFR 146.113).

-- A health plan offered under chapter 89 of title 5, United States Code (Federal Employees Health Benefits Program).

-- A public health plan. (For purposes of this section, a public health plan means any plan established or maintained by a State, county, or other political subdivisions of a State that provides health insurance coverage to individuals who are enrolled in the plan.)

-- A health benefit plan under section 5(e) of the Peace Corps Act (22 U.S.C. 2504(e)).

The term “creditable health coverage” does not include coverage consisting solely of coverage of excepted benefits including limited excepted benefits and non-coordinated benefits. (See 45 CFR 146.145)

• Emergency medical condition has the meaning assigned at §457.402.

• Emergency services has the meaning assigned in §457.402.

• Employment with a public agency has the meaning assigned in §457.301.

• Family income means income as determined by the State for a family as defined by the State.

• Federal fiscal year starts on the first day of October each year and ends on the last day of September.

• Fee-for-service entity has the meaning assigned in §457.902.

• Grievance has the meaning assigned in §457.902.

• Group health insurance coverage means health insurance coverage offered in connection with a group health plan as defined at 45 CFR 144.103.

• Group health plan means an employee welfare benefit plan, to the extent that the plan provides medical care as defined in section 2791(a)(2) of the PHS Act (including items and services paid for as medical care) to employees or their dependents directly (as defined under the terms of the plan), or through insurance, reimbursement, or otherwise, as defined at 45 CFR 144.103.

• Health benefits coverage has the meaning assigned in §457.402.

• Health maintenance organization (HMO) plan has the meaning assigned in §457.420.

• Joint application has the meaning assigned in §457.301.

• Legal obligation has the meaning assigned in §457.560.

• Low-income child means a child whose family income is at

or below 200 percent of the poverty line for the size family involved.

• Managed care entity (MCE) has the meaning assigned in §457.902.

• Medicaid applicable income level means, with respect to a child, the effective income level (expressed as a percentage of the poverty line) that has been specified under the State plan under title XIX (including for these purposes, a section 1115 waiver authorized by the Secretary or under the authority of section 1902(r)(2)), as of March 31, 1997, for the child to be eligible for medical assistance under either section 1902(l)(2) or 1905(n)(2) of the Act.

• Medicaid expansion program means a program where a State receives Federal funding at the enhanced matching rate available for expanding eligibility to targeted low-income children.

• Post-stabilization services has the meaning assigned in §457.402.

• Poverty line/Federal poverty level means the poverty guidelines updated annually in the **Federal Register** by the U.S. Department of Health and Human Services under authority of 42 U.S.C. 9902(2).

• Preexisting condition exclusion has the meaning assigned at 45 CFR 144.103, which provides that the term means a limitation or exclusion of benefits relating to a condition based

on the fact that the condition was present before the first day of coverage, whether or not any medical advice, diagnosis, care or treatment was recommended or received before that day. A preexisting condition exclusion includes any exclusion applicable to an individual as a result of information that is obtained relating to an individual's health status before the individual's first day of coverage, such as a condition identified as a result of a pre-enrollment questionnaire or physical examination given to the individual, or review of medical records relating to the pre-enrollment period.

• Premium assistance for employer-sponsored group health plans means State payment of part or all of premiums for group health plan or group health insurance coverage of an eligible child or children.

• Public agency has the meaning assigned in §457.301.

• Separate child health program means a program under which a State receives Federal funding from its title XXI allotment under an approved plan that obtains child health assistance through obtaining coverage that meets the requirements of section 2103 of the Act.

• State means all States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa and the Northern Mariana Islands.

• State health benefits plan has the meaning assigned in

§457.301.

• State plan means the approved or pending title XXI State child health plan.

• State program integrity unit has the meaning assigned in §457.902.

• Targeted low-income child has the meaning assigned in §457.310.

• Uncovered child means a child who does not have creditable health coverage.

• Well-baby and well-child care services means regular or preventive diagnostic and treatment services necessary to ensure the health of babies and children as defined by the State. For purposes of cost sharing, the term has the meaning assigned at §457.520.

We note that comments concerning definitions that are specific to certain subparts are discussed at the opening of those subparts. We received the following comments on the terms defined in this section:

Comment: We received a comment suggesting that we use the terms “SCHIP”, “Medicaid expansion program” and “separate child health program” consistently throughout the regulation. The commenter noted that we repeatedly use the term “SCHIP” when it appears the term “separate child health program” is meant.

Response: We agree with the commenter and have revised the

rule for clarity and consistency. Throughout this regulation, we use the terms “Medicaid expansion program” and “separate child health program” to refer to the different types of programs that States may establish under title XXI. These terms are defined at §457.10. We use the term “SCHIP”, also defined at §457.10, to refer to the State’s title XXI program regardless of whether it is a Medicaid expansion program or a separate child health program.

Also for purposes of clarity and consistency, we have added definitions of the terms “applicant”, “enrollee”, “health care services”, and “uninsured or uncovered child” to the definitions section of the final rule. We felt that it was important to make clear both the distinctions and the similarities between these two groups of children for purposes of SCHIP (either individually or through action by family or other interested parties).

“Applicant” means a child who has filed an application (or who has had an application filed on his/her behalf) for health benefits coverage through SCHIP. A child is an applicant until the child receives coverage through SCHIP. An “enrollee” is a child who receives health benefits coverage through SCHIP. “Health care services” means any of the services, devices, supplies, therapies, or other items listed in §457.402(a). “Uncovered child or uninsured child” means a child who does not have creditable health coverage.

We have added a few definitions related to presumptive eligibility under Subpart C, including “qualified entity”, “presumptive income standard” and “period of presumptive eligibility”. The Benefits Improvement and Protection Act of 2000 (BIPA) (Pub. L. 106.554) expanded the list of entities specifically eligible to make presumptive eligibility determinations and extended the provision related to presumptive eligibility for children under Medicaid to separate child health programs.

Finally, we have added the definition of “health services initiatives” to the overall definitions section because it is used throughout the regulation. This term was previously discussed only in Subpart J, in relation to the waiver authority to provide services through community-based delivery systems.

Comment: One commenter indicated that the definition of AI/AN should include a reference to the standards used by the Secretary to define an AI/AN. The commenter agreed with our use of section 4(c) of the Indian Health Care Improvement Act, 25 U.S.C. 1603(c) to define AI/AN. The commenter believes our proposed definition will assist States in meeting requirements regarding the AI/AN population.

Another commenter indicated that our use of the definition of AI/AN set forth in the Indian Health Care Improvement Act is appropriate for purposes of the premium and cost sharing

exclusion. However, the commenter notes that the proposed definition of AI/AN set forth at §457.10 is narrowed by the cost-sharing provisions at §457.535, which specify that only American Indians and Alaska Natives who are members of a Federally recognized tribe are excluded from cost-sharing charges. The commenter believes that the definition of AI/AN at §457.535 is more restrictive than that set forth in the Indian Health Care Improvement Act and has no basis in title XXI. The commenter believes that the definition at §457.535 is also inconsistent with the proposed consultation provisions of §457.125(a), which expressly requests that States consult with "Federally recognized tribes and other Indian tribes and organizations in the State ..." The commenter asserted that there is little point in consulting with non-Federally recognized tribes about enrollment in SCHIP if the children of those tribes are not excluded from premiums and cost sharing.

Response: We have modified the definition of AI/AN, after discussion with IHS, to make the definition as consistent as possible with both the Indian Health Care Improvement Act (IHCIA) and the Indian Self Determination Act. The definition no longer includes descendants, in the first or second degree, of members of federally recognized tribes, and we have removed the reference in paragraph (4) to regulations to be promulgated by the Secretary. We believe that this definition is substantially

equivalent to, and no more restrictive than, the definition in the IHCIA, but is consistent with the flexibility available under the Indian Self Determination Act. We have used this definition because it gives full weight to federally recognized government-to-government relationship between the federal government and tribal governments. We do not intend, however, to restrict the States' ability to engage in a wider scope of consultation in developing their programs.

Comment: One commenter indicated that the definition of "child" is inconsistent with their State's statute which considers children up to age 19 for child support purposes. Another commenter supports HCFA's definition of family income as it gives States the flexibility to define income and family.

Response: The definition of "child" was taken from section 2110(c) of the Act. With regard to the definition of family income, we appreciate the support and want to give States as much flexibility as possible when defining this aspect of their SCHIP programs.

Comment: We received a comment on the definition of premium assistance for employer-sponsored group health plans. The commenter states that according to the definition of this term at §457.10, a State can pay all or part of the premium. The commenter notes that this definition appears to conflict with proposed §457.810(b)(2)(i) and (ii) which require that an

employer contribute 60 percent of the cost of the premium, or a lower amount if the State can show that the average contribution in the State is lower than 60 percent, as a protection against substitution of coverage.

Response: The commenter is correct. In order for the purchase of employer-sponsored coverage to be cost-effective in accordance with §457.810(b)(2), it was our intent to say that the State can pay for all or **part** of the enrollee's share of the premium for group health plan coverage of an eligible child or children. It is unlikely that a State's payment of **all** of the premium would meet the cost-effectiveness test. Accordingly, we have revised the definition of premium assistance for employer-sponsored group health plans to indicate that a State can pay for all or part of the enrollee's share of the premium.

It should also be noted that, in this final rule we have made some significant changes in the list of terms defined, in order to clarify terminology for health benefits coverage provided through a group health plan or group health coverage. We defined the term "premium assistance for employer-sponsored group health plans." We also used the term "employer-sponsored group health plan" and "employer-sponsored group health plan coverage" throughout the proposed rule.

In hopes of simplifying discussions of our policy, we have elected to create a new term that is intended to be inclusive of

all types of group health coverage. We no longer use the term "employer-sponsored" prior to references to group health plan or group health insurance coverage in this final rule. We believe that the use of the term "employer-sponsored insurance" or "employer-sponsored group health plan" could unintentionally narrow the scope of permitted premium assistance programs and wanted to avoid that result. Under HIPAA, the term "group health plan" has a very specific legal meaning and refers to a broad array of coverage arrangements; it does not solely refer to health plans offered by a single employer. Therefore, we did not want to cause confusion around the possible scope of programs permitted under Title XXI by using the term "employer-sponsored" in connection with provisions relating to premium assistance programs and rather, refer to all of these types of programs accordingly.

Comment: One commenter suggested that HCFA include in the final rule the definition of "health services initiatives" set forth in the August 6, 1998 letter to State Health Officials. In the letter, the term is defined as "activities that protect the public health, protect the health of individuals or improve or promote a State's capacity to deliver public health services and/or strengthens resources needed to meet public health goals."

Response: We agree with the commenter. We have added the definition of "health services initiatives" as set forth in the

August 6, 1998 letter.

Comment: Commenters asserted that the definition of well-baby and well-child care for purposes of cost sharing (set forth at §457.520) be used in three other sections of the regulation: Definitions and use of terms §457.10; Child health assistance and other definitions §457.402; and Health benefits coverage options §457.410(b)(2). One commenter urged that our recognition in §457.520 that preventive oral health care is part of well-baby and well-child care be extended to the definition of this term at §§457.10, 457.402, 457.410(b)(2). The commenter believes that the definition of well-baby and well-child care which includes preventive oral health care should not be treated simply as a category of services left to State discretion for definitional purposes. The commenter noted that the Medicaid program provides for a comprehensive set of services and screenings for oral health care services through EPSDT services. The commenter believes that a clearly defined set of well-baby and well-child care benefits is essential to ensuring a baseline of care in separate child health programs.

Response: EPSDT services are required to be provided to eligible Medicaid beneficiaries under the age of 21 and are defined at section 1905(r) of the Act. Title XXI does not contain the same type of definition for well-baby and well-child care provided under a separate child health program. Therefore,

States have the flexibility to design health benefits packages that best fit their needs and resources. In addition, for States that have elected benchmark plans as their health benefits option, these plans may already include standards for furnishing well-baby and well-child care; and it would be inconsistent with the flexibility provided by the statute in this area, as well as cause confusion among plans and providers if we implemented another definition.

Although most separate child health plans do include some type of dental coverage, it is by no means common. Therefore, it is not appropriate to require these services as part of well-baby well-child care. If dental coverage is provided, however, it should be included as part of well-baby well-child care for purposes of cost sharing. Specifically, dental care can be viewed as the oral health equivalent of immunizations in that it can prevent most cavities and subsequent tooth loss, both of which are highly correlated to poverty and lack of access to dental care. Second, we found that the prevailing practice among State employee plans and large HMOs is to pay 100 percent for any routine preventive and diagnostic dental benefits offered for children. Therefore, consistent with section 2103(e)(2) of tjhe Act “no cost-sharing on benefits for preventive services” cost sharing may not be applied to these services, if a State chooses to offer them under the State plan.

Comment: Commenters suggested including the word "adolescent" in the definition of well-baby and well-child care services. The commenters believe that we should focus on the unique health needs of adolescents, which make up approximately 39 percent of SCHIP eligible youth because their health needs differ from those of younger children. The commenters also urged HCFA to list specifically in the regulation medical sources that have guidelines for regular or preventive diagnostic and treatment services for infants, children and adolescents. These sources should include the American Academy of Pediatrics' "Guidelines for Health Supervision of Infants, Children and Adolescents," the American Medical Association's "Guidelines for Adolescent Preventive Services," and the American College of Obstetricians and Gynecologists' "Primary and Preventive Health Care for Female Adolescents."

Response: We have not adopted this suggestion. The definition of child for purposes of SCHIP at §457.10 and section 2110(c)(1) of the Act indicates that a "child" is an "individual under the age of 19." Adolescents under age 19 are clearly included in this age group and therefore we have not included this term in referring to well-baby and well-child care. We encourage States to adopt one of the guidelines mentioned by the commenter, but we have not required adherence to a particular definition.

The commenters urged HCFA to list specifically in the regulation medical sources that have guidelines for regular or preventive diagnostic and treatment services for infants, children and adolescents. The examples of medical sources that are listed in the preamble are meant to serve as recommendations not requirements. The American Medical Association's "Guidelines for Adolescent Preventive Services," is an acceptable medical standard of practice for adolescents and States may use this standard if they choose.

Comment: We received numerous comments on proposed §457.402(b) and (c), which set forth the definitions of emergency medical condition and emergency services, respectively. Many commenters supported the use of the prudent layperson standard in defining emergency services. Several commenters encouraged HCFA to retain this language because some State Medicaid programs and managed care organizations are not in compliance with the prudent layperson standard and have denied payment for emergency services because prior authorization was absent. The commenters recommended that HCFA closely monitor the States' programs and managed care organizations on this issue.

Response: We note the support for this provision. With respect to the definition of emergency services under a separate child health plan, States will need to review their contracts with managed care organizations and may need to revise their

contracts in order to comply with this requirement. HCFA will monitor States for compliance with this requirement as described in §457.40 of the final regulation.

Comment: One commenter stated that the required emergency care provisions may disqualify many employer plans. The commenter agreed that such policies can enhance access to emergency care. However, the commenter noted that States using premium assistance programs to subsidize employer-sponsored coverage lack control over emergency coverage. Unlike health plans with direct contracts to provide Medicaid or SCHIP services, requirements for employer-sponsored plans are set by State legislative mandate or dictated by the insurance market. If employer-sponsored plans do not adopt the prudent layperson standard or abandon pre-authorization for emergency care, their coverage may not qualify for SCHIP premium assistance, despite other elements that facilitate emergency care. The emergency care provisions could therefore pose a major barrier to using premium assistance programs for SCHIP purposes.

The commenter recommended that HCFA recognize that the emergency care requirements of the proposed regulations may exclude many valuable employer plans from SCHIP premium assistance programs. To facilitate the use of premium assistance and to reflect the flexibility provided by title XXI, the commenter suggests that HCFA should consider State approaches to

ensuring access to emergency care on a case-by-case basis.

Response: We appreciate the recognition that the prudent layperson standard enhances access to emergency care. While we understand the commenter's concerns about the difficulty posed by these requirements if States seek to provide premium assistance for available group health plan coverage, we cannot permit States to deny emergency care to children covered through group health plans. While we encourage States to provide premium assistance for group health plan coverage, it is important that all SCHIP enrollees receive necessary emergency care. States will need to carefully review group health plans to determine whether the required emergency services provisions required by this regulation are in place. If they are not, the State must disqualify those plans from participation in the program or ensure that these requirements are met by providing coverage for emergency services through a wrap-around coverage package to supplement the group health plan coverage.

Comment: One commenter noted that the definition of emergency services should include the availability of necessary resources to evaluate and treat illness and injury.

Response: We have revised the definition of emergency services to clarify the scope of such services. Because the terms "emergency medical condition" and "emergency services" are used throughout this final regulation, we have moved the

definitions for these terms to §457.10. Section 457.10 defines "emergency services," in part, as services that are "needed to evaluate or stabilize an emergency medical condition." "Emergency medical condition" is defined as a medical condition manifesting itself by acute symptoms of sufficient severity such that the absence of immediate medical attention could result in: serious jeopardy to the health of the individual or, in the case of a pregnant woman, the health of a woman or her unborn child; serious impairment of bodily function; or serious dysfunction of any bodily organ or part. Section 457.495 requires that States describe in their State plan the methods they use to assure the quality and appropriateness of care and access to services covered under the plan. Specifically, States must assure access to emergency services. We are not including requirements for State monitoring of such services in the definition because we address such monitoring separately at §457.495. Compliance with that section includes an assurance that enrollees have access to required emergency services.

Comment: One commenter referenced comments on the proposed Medicaid managed care rules that concerned consistency with Emergency Medical Treatment and Active Labor Act (EMTALA) requirements. The commenter suggested HCFA should coordinate its efforts to enforce relevant requirements for coverage of emergency services with EMTALA enforcement, and should work with

OIG, State Medicaid agencies, health plans, and children's health programs to protect Medicare, Medicaid, and SCHIP enrollees.

Response: The comments submitted on the Medicaid managed care regulation are beyond the scope of the proposed rule. Responses to comments received on the Medicaid managed care proposed rule will be addressed in the final publication of that regulation.

With respect to the issue of consistent Federal rules, we are mindful of other definitions of emergency services and have attempted to reconcile our approach with other approaches to the extent permitted by the statute. As for coordination of enforcement efforts, HCFA will monitor the operation of State plans as described in §457.40 of this final regulation and work with States and other Federal agencies to the extent possible in enforcing the requirements relating to coverage of emergency services.

Comment: One commenter mentioned the need to provide for appropriate payment to hospitals for services provided within the scope of the hospital's obligations under EMTALA. Hospitals feel that if the government requires certain medical screening and other stabilizing treatment, the government should also address how hospitals will be paid for these services. They also noted that obtaining payment for services covered under the prudent layperson standard will help to address the financial burden

borne by hospitals.

Response: We refer the commenter to §457.940 for information on payment rates under separate child health plans. We encourage States to ensure that provider payments are adequate to promote an adequate level of provider access and provider participation and the appropriate provision of services.

Comment: One commenter noted that freestanding urgent care facilities must have the capability to identify children with emergency conditions, stabilize them, and provide timely access to further necessary care. The commenter also stated that urgent care facilities must have appropriate pediatric equipment and staff trained and experienced to provide critical support until patients are transferred for definitive care. In addition, the commenter noted that it is necessary for urgent care facilities to have prearranged access to comprehensive emergency services through transfer and transport agreements to which both facilities adhere. Available and appropriate modes of transport should be identified in advance.

The commenter also noted that after-hours urgent care clinics used as a resource for pediatric urgent care, should solicit help from the pediatric professional community. Moreover, in this commenter’s view, pediatricians who are prepared to assist in the stabilization and management of critically ill and injured children should be accessible.

Pediatricians responsible for managing the health care of children may occasionally need to use the resource of urgent care facilities after hours. When such clinics are recommended to patients, pediatricians should be certain that the urgent care center is prepared to stabilize and manage critically ill and injured children.

Response: As noted earlier, under §457.495 of this final regulation, States must assure appropriateness of care and access to emergency services. A State has flexibility to determine the providers who furnish services, including emergency services. However, a State using free-standing or urgent care facilities as providers under its SCHIP plan for the delivery of emergency services, must meet the requirements of §457.495 in doing so.

As far as the suggestion that available and appropriate modes of transport be identified in advance, we encourage States and urgent care providers to have arrangements to ensure that transportation is available to appropriate facilities; however the terms of such arrangements are left to States' discretion.

Comment: One commenter is pleased with the guaranteed access to emergency services without prior authorization; however, the commenter was concerned about what happens in a State that provides for no mental health coverage in its State plan.

Response: Under a separate child health program, States are

given flexibility, within the confines of the health benefits coverage options outlined in §457.410, to design their benefit packages. There is no requirement for a State to provide mental health services under its State plan unless the health benefits coverage option selected by the State includes those services. However, we encourage States to provide coverage for mental health services. In addition, we note that emergency mental health services that meet the prudent layperson definition of "emergency medical condition" must be available regardless of whether mental health services are covered under the separate child health program.

Comment: Three commenters indicated that children who were covered by section 1115 demonstration projects with a limited benefit package should not be considered to have been recipients of Medicaid. The commenters urged HCFA to provide clarification on the treatment of children eligible for Medicaid under a section 1115 demonstration project that limited eligibility or provided a limited range of services and the availability of enhanced matching for such children.

Response: We agree with the general principle expressed by the commenters that it would not further the purpose of title XXI to exclude from children who were eligible only under a section 1115 demonstration project that was significantly limited in scope and, therefore, was not generally comparable with

traditional Medicaid coverage.

In regard to the definition of “targeted low income child” at section 2110(b)(1)(C) of the Act, children are excluded from coverage in a separate child health program only when they are found eligible for Medicaid. These comments are relevant, however, the interpretation of the general condition set forth at section 2105(d)(1) of the Act which was implemented by the regulatory provision at 42 CFR 457.622(b)(5), contained in the financial rule published May 24, 2000 (65 FR 33616). That provision merely codified section 2105(d)(1) into regulations without interpretation. In addition, the factors discussed by the commenters affect how we look at “Medicaid applicable income level” which is part of the financial need standard that a targeted low-income child must meet.

We have added an additional paragraph to §457.310 that clarifies that policies of the State’s title XIX plan do not include statewide section 1115 demonstration projects that covered an expanded group of eligible children but that either (i) did not provide inpatient hospital coverage, or (ii) did not impose a general time limit on coverage but did limit eligibility by both allowing only children who were previously enrolled in Medicaid to qualify and imposing premiums as a condition of participation in the demonstration.

We have excluded these types of demonstrations because they

were particularly narrow in scope and not of the type intended to be encompassed by the reference to “Medicaid applicable income level” in section 2110(b)(4) of the Act. This provision ensures that separate child health programs serve low-income children whose income exceeds preexisting Medicaid income levels. However, we do not believe the provision was intended to preclude States from claiming enhanced matching funds for expanded coverage to children whose income is below the demonstration project eligibility thresholds in place as of March 31,1997, if those programs did not offer comprehensive coverage or limited eligibility to individuals who were previously enrolled in Medicaid. Our experience with SCHIP and our increased understanding of how this provision is affecting States’ ability to expand coverage have led us to agree with the commenters that an overly broad interpretation of the provision is contrary to the primary purpose of the statute. We have clarified this provision in the final rule accordingly. As a result, children previously eligible for these types of demonstration projects may be included in a separate child health program as a “targeted low-income child.”